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REMARKS

Claims 1-37 are pending in the present Application. Claims 2-7, 12, 13, 15, 16, 20-29, and 31-37 have been withdrawn from consideration, and claims 1 and 11 have been amended leaving Claims 1-37 for consideration upon entry of the present Amendment.

The Specification has been amended to correct certain typographical errors, as explained in detail below.

Support for the amendment to claim 1 can be found in the specification on Page

Support for the amendment to claim 11 can be found in claim 11 itself.

No new matter has been introduced by these amendments. Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Specification

The Specification is objected to for not giving the relationship between the present application and the parent and for not containing the current status of the parent. Both of the defects have been corrected.

The title stands objected to as allegedly not descriptive of the invention. The title has been changed to "Implant Having a Tissue/Implant Interface".

Claim Objections

Claim 11 stand objected to for the use of the term "acids". This term has been amended to "acid" as suggested by the Examiner.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1, 17-19, and 30 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Patent No. 5,609,629 to Fearnot et al (hereinafter "Fearnot"). Applicants respectfully traverse this rejection.

The present application is directed to an implant having a tissue/implant interface, comprising an implant having an outer surface; a bioactive polymer layer adjacent to at least a portion of the outer surface; and controlled release nanoparticles, liposomes, or microspheres containing a tissue response modifier in the bioactive polymer layer,

wherein the controlled release nanoparticles, liposomes, or microspheres provides the tissue response modifier to the site of implantation in a quantity effective to control tissue response at the site of implantation.

Fearnot is directed to a implantable medical device (10) such as a coronary stent having a structure (12), a layer of bioactive material (18) positioned over the structure, and a porous layer (20) positioned over the bioactive material layer. (Abstract) The device is illustrated, for example, in Figure 1. The bioactive layer may be, for example, an anti-inflammatory steroid, heparin, dexamethasone, etc. (Col. 3, ll. 30-35) The porous layer is "composed of a polyimide, parylene or a parylene derivative applied by catalyst-free vapor deposition" which is "adequate to provide controlled release of the bioactive material". (Col. 3, ll. 50-54) Alternatively, the porous layer can be applied by plasma deposition and comprise "poly(ethylene oxide), poly(ethylene glycol), poly(propylene oxide) and silicone, as well as polymers of methane, tetrafluoroethylene (including TEFLON brand polymers), tetramethyldisiloxane, and others". (Col. 4, ll. 18-23) The device may include additional layers of bioactive material which "can be placed directly atop one another or can be separated by additional porous polymer layers between each of them". (Col. 4, ll. 23-28) The bioactive material may be deposited "as a layer of particles" such as "microencapsulated particles, dispersed in liposomes, adsorbed or absorbed into small carrier particles". (Col. 14, ll. 12-28) It is then stated "In any event, once then bioactive material layer 18 is in place, the at least one porous layer 20 is then applied over the at least one bioactive material layer 18". (Col. 14, ll. 29-21) Thus, regardless of the form of the bioactive material layer, the bioactive material and the porous layer are discrete layers on the substrate.

In making the rejection, the Examiner states "Fearnot anticipates the claim language where the implant with the outer surface...by implant (10)". "The bioactive polymer layer with nanoparticles of liposomes as claimed is met by the disclosure on column 14, lines 12-29 of Fearnot". Also, "the bioactive tissue response modifier as claimed is disclosed on column 3, lines 30-49 of Fearnot". (Paper 16, Page 3) Applicants submit that Fearnot does not disclose "controlled release nanoparticles, liposomes, or microspheres containing a tissue response modifier in the bioactive polymer layer" as now claimed in the present Application.

To anticipate a claim, a reference must disclose each and every element of the claim. *Lewmar Marine v. Varient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). The present application claims an implant comprising "controlled release nanoparticles, liposomes, or microspheres containing a tissue response modifier in the bioactive polymer layer". Fearnot, in contrast, teaches an implant in which a porous layer of a controlled release polymer is disposed on a layer of bioactive material. There is no teaching or suggestion in Fearnot that the bioactive material be in the porous layer. Thus Fearnot is missing an element of the present claims. In addition, Fearnot also fails to render the present claims obvious. Given that the porous layer is deposited by vapor or plasma deposition, it is not obvious that one of skill in the art could or would incorporate a bioactive material into such a layer.

For at least the foregoing reasons, reconsideration and withdrawal of the rejections over Fearnot are requested.

Claims 1, 17-19, and 30 stand rejected under 35 U.S.C. § 102(b) or (e), as allegedly anticipated by U.S. Patent No. 5,801,033 to Hubbell et al (hereinafter "Hubbell"). Applicants respectfully traverse this rejection.

Hubbell is directed to methods of formation of biocompatible membranes around biological materials. The biocompatible membrane is the photopolymerization product formed by a macromer such as polyethyelene glycol, a phototinitiator, an optional cocatalyst, and an optional accelerator. (Col. 7, ll. 25-35) The biological material may be a "microencapsulated material as a core about which the macromer is polymerized in a suspension polymerization reaction". (Col 8, ll. 1-3) In another method, interfacial polymerization is used to polymerize the macromer onto a microencapsulated biological material. (Col. 8, ll. 46-49) In the direct interfacial polymerization method, interfacial polymerization is used "to form a membrane directly onto the surface of the biological material". (Col. 9, ll. 25-27)

In making the rejection, the Examiner states ""Hubbell anticipates the claim language where the tissue response modifier is the agent or material released by the encapsulated cells to have a therapeutic purpose in the patient". The Examiner further states "the gels of Hubbell are hydrogels". (Paper 16, Page 3) Applicants submit that Hubbell does not disclose "controlled release nanoparticles, liposomes, or microspheres containing a tissue response modifier in the bioactive polymer layer" as now claimed in

the present Application.

The present claims are directed to an implant comprising a bioactive polymer layer adjacent to at least a portion of the outer surface; and controlled release nanoparticles, liposomes, or microspheres containing a tissue response modifier in the bioactive polymer layer. Hubbell fails to anticipate the present claims because Hubbell at least fails to teach or disclose this element of the present claims. Hubbell is directed to methods of forming biocompatible membranes around biological materials. In some cases, such as in the interfacial polymerization method, the biocompatible membrane is formed on the surface of the biological material and "results in the smallest capsules". (Col. 9, ll. 30-31) Given this description and, for example, figures 2-4 of the application, we believe this language to mean that individual particles of biocompatible material are surrounded by a polymer coat. Similarly, in some cases, particles of the biological material are first surrounded by a material such as an alginate, and then encapsulated with a polymer. In all cases, the polymer and the biological material appear to be present as discrete layers. Thus, the biological material is in its own separate layer and is not in the polymer layer. Hubbell thus fails to disclose a tissue response modifier in a bioactive polymer layer as presently claimed.

In addition, Hubbell fails to render the present claims obvious. Hubbell teaches a method of making, for example, cells, tissues and organelles encapsulated with a membrane. (Col. 10, ll. 33-41) It would be contrary to the teachings of Hubbell to include the bioactive material in the polymer layer, as the function of the polymer layer is to encapsulate the bioactive material. For at least this reason, Hubbell also fails to render the present claims obvious.

For at least the foregoing reasons, reconsideration and withdrawal of the rejections over Hubbell are requested.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance are requested.

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If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,
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